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AMSTER, ROTHSTEIN & EBENSTEIN
90 Park Avenue
New York, NY 10016

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/26/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,143

Applicant(s)

ELLIS ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,14-17,19,20 and 86-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,12,14-17,19,20 and 86-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 9, mailed on April 22, 2003), Applicants filed a response and amendment received on July 17, 2003 (Paper No. 11). Said amendment cancelled Claims 13 and 18, amended Claim 11, and added new Claims 86-93. Thus, Claims 11, 12, 14-17, 19-20, and 86-93 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/175,828 and 08/559,303 filed on October 20, 1998 and November 15, 1995.

Information Disclosure Statement

3. The information disclosure statement filed on July 17, 2003 (Paper No. 11) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Compliance with the Sequence Rules

4. By virtue of Applicants' amendment, the instant application now fully complies with the sequence rules.

Withdrawn - Objections to the Specification

5. Previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicant's amendment describing each of the 78 sequences in the listing in the specification.
6. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.
7. Previous objection to the specification for lacking appropriate continuity data in the first paragraph is withdrawn by virtue of Applicants' amendment.
8. Previous objection to the specification for having improper citations of references is withdrawn by virtue of Applicant's amendment. The Examiner notes that Applicants' amendment has resulted in a new matter objection to the specification (below). The Examiner suggests removal of the "incorporation by reference" paragraph on page 37 and, optionally, individually incorporating by reference those references with incorporation support in the specification as originally filed.

Withdrawn - Claim Objections

9. Previous objection to Claim 13 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

Withdrawn - Claim Rejections 35 U.S.C. § 112

10. Previous rejection of Claim 18 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn by virtue of Applicant's cancellation of said claim.

New or Maintained - Claim Rejections - 35 U.S.C. § 112

11. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "*BLM* gene" is maintained. Additionally, new Claims 86-93 are added to this rejection. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the amended claim, which defines the unmutated *BLM* gene, is clear in its metes and bounds. The Examiner disagrees. Without limitation on the number of mutations, a "mutated *BLM* gene" can be virtually any gene. Although the instant specification focuses on identifying point or limited mutations in a subject's *BLM* gene, no requirement for maintaining any particular *BLM* gene character is required; no requirement of being a DNA helicase is required. Thus, the instant claim is significantly broader than implied throughout the specification. Additionally, for new Claims 86-93, there is no limitation requiring that the detected gene be SEQ ID NO:72 with the particular mutations cited since the word "characterized" does not particularly define the mutated *BLM* gene.

12. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Additionally, new Claims 86-93 are added to this rejection. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the amendment to Claim 11 obviates the rejection; this is not the case. The amendment does not limit the character of the mutated *BLM* gene in any way. In fact, the

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Examiner is amending the rejection to herein include the fact that a mutated BLM gene need not be related to Bloom's syndrome in any way. There are no particular method steps requiring the use of a nucleic acid encoding SEQ ID NO:78. Thus, the materials used to practice the method are not adequately described. As previously noted,

“a mutated BLM gene is described as SEQ ID NO:72 with any number of deletions, insertions, point mutations, and/or rearrangements mutations (see page 8). Thus unlimited mutation broadens the scope of a “mutated BLM gene” to be virtually *any* structure. In the instant specification, a single example of a human Bloom's syndrome-linked gene is described. However, in view of this broad interpretation of a “mutated BLM gene” defined in the specification, no common structure of the genus of mutated BLM genes can be recognized.”

Additionally, for new Claims 86-93, while a limited portion of the detected gene is required in the further limitations, the phrase “characterized by” does not define the overall structure of the mutant gene detected in the method. Thus, even these more limited claims lack adequate written description.

As previously noted, “the Examiner suggests adding method steps to the instant claims that utilize SEQ ID NO:72 in some hybridization step. Such claims would limit the scope of a “mutated BLM gene” by virtue of the hybridization language.”

13. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Additionally, new Claims 86-93 are added to this rejection. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the amendment to Claim 11 obviates the rejection; this is not the case. As noted above and previously,

“the definition of mutated BLM gene is so broad that numerous species of the genus would not be recognized by common techniques in the art. As such, these

structurally dissimilar, mutated BLM genes would require undue experimentation for their detection. ...

The specification describes examples of using the disclosed BLM gene to identify BLM genes in other subjects. The subject's BLM gene can then be compared to the wild type, or normal, BLM gene. No working examples are described wherein the mutated BLM gene is significantly different in structure from the disclosed BLM gene. No guidance for surmounting such problems is offered. While the relative skill of those in the prior art is high, the predictability of identifying mutated BLM genes is strictly linked to the ability to find the mutant gene by its structural relationship to that which is disclosed in the instant specification. The predictability of finding highly dissimilar sequences is very low. Thus, the instant claims are not enabled to the full extent of their scope."

NEW ISSUES

Objections to the Specification

14. The amendment filed July 17, 2003 (Paper No. 11) is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- a) In the paragraph bridging pages 3-4, "band q26.1" and "35(1): 118-128, 1996" (the publication citation).
- b) In the paragraph bridging pages 4-5, "Am. J. Hum. Genet. 57(5):1019-27" and "Erratum in Am. J. Hum. Genet. 58(1):254, 1996".
- c) In the paragraph bridging pages 13-14, "49(5):223-231, 1996".
- d) In the paragraph on page 26, "The Ashkenazic Jewish Bloom syndrome mutation blmAsh is present in non-Jewish Americans of Spanish ancestry, Am. J. Hum. Genet. 63(6): 1685-93, 1998".

By addition of a complete citation in conjunction with the note on page 37 incorporating by reference all publications mentioned in the specification, the entire contents of any publication added in the amendment of July 17, 2003 would be incorporated by reference but it is not clear that these references, in their entirety, are supported in the specification as originally filed.

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Applicant is required to cancel the new matter in the reply to this Office Action or to cite specific page and line number where support in the original specification can be found.

The Examiner notes that Applicants' amendment in response to objections to the specification has resulted in the instant new matter objection to the specification. The Examiner suggests removal of the "incorporation by reference" paragraph on page 37 and, optionally, individually incorporating by reference those references with incorporation support in the specification as originally filed.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 86, 89, and 91 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The "insertion of A" after nucleotide 1610 is not supported in Table 1, which does not specify the nature of the nucleotide at the insertion point. Also, "nucleotides TAGATTC" is not supported in Table 1, which does not specify the nature of the nucleotide at the insertion point; only a 6 base pair for 7 base pair deletion/insertion is noted. Applicant is required to cancel the new matter in the reply to this Office Action or to cite specific page and line number where support in the original specification can be found.

Summary of Pending Issues

16. The following is a summary of the issues pending in the instant application:
- a) The amendment filed July 17, 2003 (Paper No. 11) stands objected to under 35 U.S.C. § 132, new matter.
 - b) Claims 11, 12, 14-17, and 19-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “*BLM* gene”.
 - c) Claims 86, 89, and 91 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
 - d) Claims 11, 12, 14-17, and 19-20 stand under 35 U.S.C. § 112, first paragraph, written description.
 - e) Claims 11, 12, 14-17, and 19-20 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Examiner Comments

17. The Examiner suggests claim language that uses a nucleic acid sequence encoding SEQ ID NO:78 in (a) a hybridizing step followed by (b) a sequencing step to identify mutations in a subject's *BLM* gene. Such a method would detect not only mutated *BLM* genes but also unmutated *BLM* genes (subjects free of Bloom's syndrome). Moreover, such a claim could be limited to identifying particular mutations such as in Claim 86.

Conclusion

18. Claims 11, 12, 14-17, 19-20, and 86-93 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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KMK
September 24, 2003